EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Industry platform meeting - operation of EU pharmacovigilance

15 November 2024

Goal of the presentation & contents

EUROPEAN MEDICINES AGENCY

Provide an overview of:

- **The new fee regulation**
- **Changes and benefits for industry stakeholders, including operational details**

1 **Introduction and background to the New Fee Regulation**

Patrick Lopez Fernandez, Procedure, Revenue and Expenditure, EMA

2 **Operational changes**

Mariana Rivera Vargas, Financial Initiating Agent, EMA

3 **Engagement opportunities, Q&A and closing**

Patrick Lopez Fernandez, Procedure, Revenue and Expenditure, EMA

Introduction and background to the New Fee Regulation

Patrick Lopez Fernandez, Procedure, Revenue and Expenditure, EMA

Drivers for a new fee regulation and new state from 1st Jan 2025

EUROPEAN MEDICINES AGENCY

Current state

Currently, fees levied by EMA are laid down in <u>two regulations</u>

- Council Regulation (EC) No 297/95 on the general fees for the Agency
- Regulation (EU) No 658/2014 for pharmacovigilance activities

→ **Need for harmonisation and updates**

Future state from 01 Jan 2025

EP and Council agreed on the revised EMA Fee Regulation in September 2023. Final adoption and formal publication happened on 7 February 2024 - Regulation (EU) 2024/568 with **implementation date 1st January 2025**.

The fees payable to the Agency

- will **be proportionate to the work** carried out reflecting **complex evaluations** and
- will **be based on actual costs** for the services delivered by EMA and NCA (Network remuneration based on hours recorded and roles of rapporteur / co-rapporteur)

High-level changes and benefits for Industry (H)

EUROPEAN MEDICINES AGENCY

FEE CHANGES INCLUDING ADMIN FEES

- ✓ The **update of fee structures** which are calculated per procedure and based on actual costs incurred across 30 EEA Member States and EMA
- ✓ The **introduction of new fees** for Referrals
- ✓ The **modification of administrative fees** for false SME declaration

Single framework for streamlined fee system

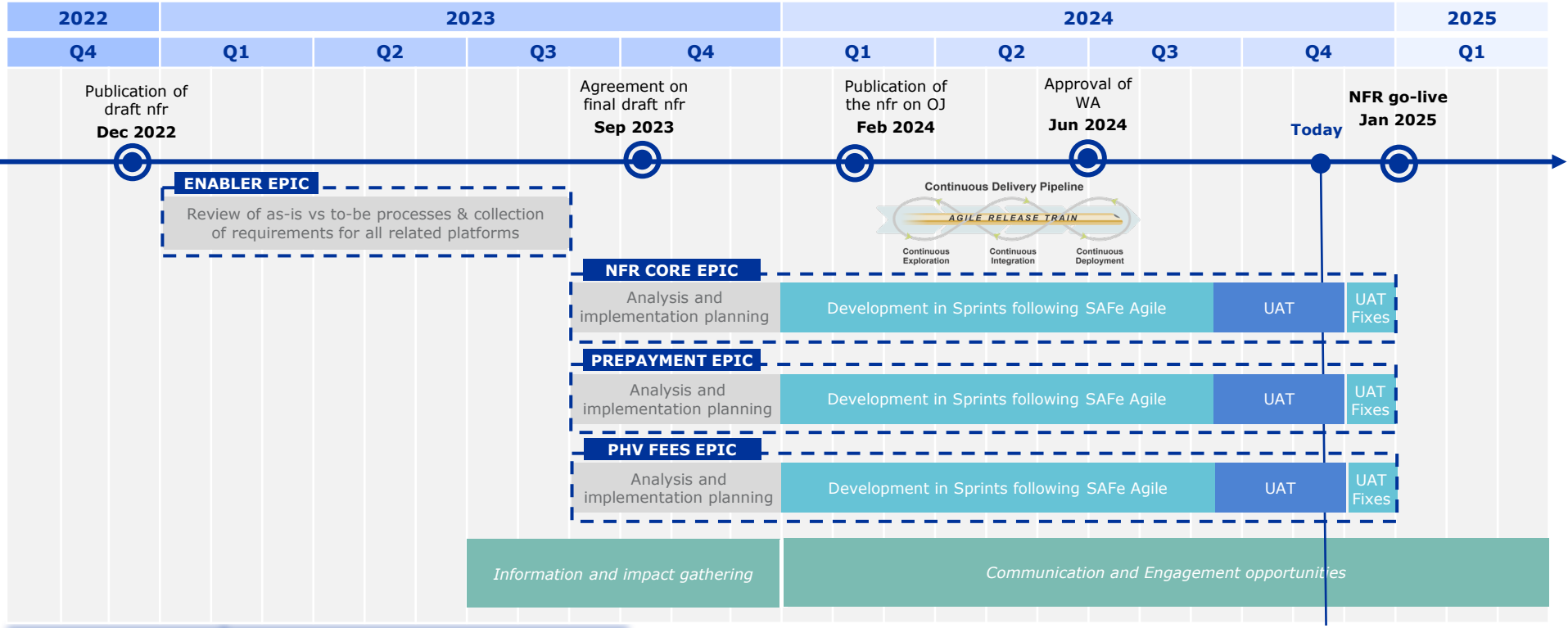
Simplification and **better understanding** of the fee system

Solid frame for **innovation** in the pharmaceutical sector through provisional incentives

Integration of applications and systems, improving the **corrections process** as well as increasing **automation**

Implementation timeline

EUROPEAN MEDICINES AGENCY



Acronyms

NFR: New Fee Regulation
OJ: Official Journal
PHV: Pharmacovigilance
SAFe: Scaled Agile Framework
UAT: User Acceptance Testing
WA: Working Arrangements

Legend

Milestone

UAT activities

Development activities

Analysis & preparatory activities

Change Mgmt activities

Updates to available regulatory guidance

EUROPEAN MEDICINES AGENCY

Documents are being updated and will be made available on EMA's website in November 2024 (Working Arrangements already published)

Currently available documentation:

- Current Fee regulations
- Explanatory note
- Implementing rules
- SME Regulation (continues to apply)

Documentation applicable starting from 1st January 2025:

- Regulation (EU) 2024/568
- SME Regulation
- Working arrangements
- Fee Q&As on EMA's website

Operational changes

Mariana Rivera Vargas, Financial Initiating Agent, EMA

Main impacted procedures and related changes (1/3)

CURRENT

FROM 1ST JANUARY 2025

PHV REFERRALS (H)

- 6 fee levels for PHV and non-PHV referrals, from which 3 (non-PHV) are waived in full.
- SME status for applicable fee incentives can be determined at latest, 30 calendar days from the date of the invoice.
- Penalty for false SME declaration is 10% of applicable fee.

- 9 different fee levels including PHV and non-PHV referrals.
- The fee for 3 types of referrals is waived in full,
- SME status for applicable fee incentives is determined on the notification date of the referral procedure.
- Penalty for false SME declaration is a fixed amount regardless of the applicable fee.

Please note: this is not an exhaustive list of all fee changes, further details will be included in relevant guidance.

Main impacted procedures and related changes (2/3)

EUROPEAN MEDICINES AGENCY

CURRENT

ANNUAL PHV FEE (H)

- Currently charged
- SME status for applicable fee incentives can be determined at latest, 30 calendar days from the date of the invoice.
- Penalty for false SME declaration is 10% of applicable fee

FROM 1ST JANUARY 2025

- Changes to Fee Amounts
- SME status for applicable fee incentives is determined on the 1st of July.
- Penalty for false SME declaration is a fixed amount regardless of the applicable fee.

PERIODIC SAFETY UPDATE REPORT (PSUR)

- Currently charged
- SME status for applicable fee incentives can be determined at latest, 30 calendar days from the date of the invoice.
- Penalty for false SME declaration is 10% of applicable fee

- Changes to Fee Amount
- The SME status for applicable fee incentives is determined on the EURD Data Lock Point (DLP).
- Penalty for false SME declaration is a fixed amount regardless of the applicable fee.

Please note: this is not an exhaustive list of all fee changes, further details will be included in relevant guidance.

Main impacted procedures and related changes (3/3)

EUROPEAN MEDICINES AGENCY

CURRENT

FROM 1ST JANUARY 2025

POST-AUTHORISATION SAFETY STUDIES (H) (PASS)

- Currently charged
- SME status for applicable fee incentives can be determined at latest, 30 calendar days from the date of the invoice.
- Penalty for false SME declaration is 10% of applicable fee

- Changes to Fee Amount
- SME status for applicable fee incentives is determined on procedure submission date.
- Penalty for false SME declaration is a fixed amount regardless of the applicable fee.

Please note: this is not an exhaustive list of all fee changes, further details will be included in relevant guidance.

Engagement opportunities, Q&A and closing

Patrick Lopez Fernandez, Procedure, Revenue and Expenditure, EMA

Industry stakeholders' engagement opportunities

EUROPEAN MEDICINES AGENCY

Public System Demo

12 December 2024

Useful materials and past events: LINK

For any questions, please **email NFR@ema.europa.eu**